

REMARKS

This application has been reviewed in light of the Office Action dated February 18, 2003. Claims 1-93 are pending in the application. Claims 21, 22, 24, 26, 32-59, 61, 66-68, 73-90 and 93 are withdrawn from consideration. Claims 1-9, 11, 14-20, 23, 25, 27-31, 60, 62-65, 69, 70, 72, 91 and 92 are amended in a manner that Applicants believe overcome the rejections in the Office Action. Support for the amendments can be found throughout the specification and figures of the present disclosure and recite aspects of the disclosure that Applicants are believed to be entitled. No new matter or issues are believed to be introduced by the amendments. Claims 10, 12 and 13 are cancelled without prejudice. Applicants reserve the right to prosecute the subject matter of any cancelled claims in continuing applications.

In the Office Action, the election requirement was made final. The Examiner acknowledged Applicants' timely transversal of the election requirement and rejoined claims 14, 17 and 70 as requested. Applicant's provisional election, with transverse, of species under the Examiner's Requirement for Restriction is made without prejudice to filing of a divisional application for the non-elected claims. Applicants further contend that the election of species and the claims reading thereon is made without prejudice to continued prosecution of claims relating to alternate species identified by the Examiner upon a finding of allowability of a generic claim.

Applicants gratefully acknowledge the allowability of the subject matter recited in claims 3-4, 8-9, 17, 25, 29-31, 60, 62 and 71. Applicants, however, respectfully submit that in view of the amendments and remarks herein, all claims presently pending in the application are allowable over the art of record. It is noted that, in the Office Action, independent claim 71 was referred "to as being dependent upon a rejected base claim..." However, claim 71 is independent and, therefore, allowable.

In the Office Action, the specification was objected to as failing to provide proper antecedent basis for the claimed subject matter. With regard to "tabs," in the present application attention is directed to, for example, the DETAILED DESCRIPTION OF THE INVENTION, page

12, lines 20-21. With regard to "guide surfaces," in the present application attention is directed to, for example, the DETAILED DESCRIPTION OF THE INVENTION, page 15, lines 17-19. With regard to "double walled needle," in the present application attention is directed to, for example, the DETAILED DESCRIPTION OF THE INVENTION, page 25, lines 1-2. Reconsideration and withdrawal of the rejections are respectfully requested.

In the Office Action, claims 1-2, 69, 70, 72 and 91-92 were rejected under 35 U.S.C. §102(b) over U.S. Patent No. 5,925,020 to Nestell (Nestell '020). However, it is respectfully submitted that independent claim 1, claim 2 depending therefrom, independent claim 69, claim 70 depending therefrom, independent claim 72, independent claim 91 and claim 92 ultimately depending from independent claim 5, clearly and patentably distinguish over the Nestell '020 patent.

Independent claim 1, as amended, of the present application recites, *inter alia*, "[a] medical needle shield apparatus comprising: a monolithic needle hub including a collar; and a shield having a proximal end receivable by the collar in an interlocking engagement and including a plurality of hingedly connected segments..."

Independent claim 5, as amended, of the present application recites, *inter alia*, "...a needle hub having a collar...and a shield having a proximal end, a distal end and a lock disposed therebetween, the proximal end of the shield being receivable within the...collar in an interlocking engagement, the shield being manually extensible from a retracted position to an extended position wherein the lock captures a portion of the needle disposed proximal to the distal end of the needle in a configuration to prevent displacement of the shield from the extended position and the distal end of the shield encloses at least a portion of the distal end of the needle."

Independent claim 69, as amended, of the present application recites, *inter alia*, "...a needle hub means...and a shield means...for engaging the needle hub means in an interlocking engagement, the shield means being manually extensible between a retracted position and an extended position wherein the lock captures a portion of the needle disposed proximal to the distal end of the needle in a configuration to prevent displacement of the shield means from the

extended position and the distal end of the shield means encloses at least a portion of the distal end of the needle.”

Independent claim 72, as amended, of the present application recites, *inter alia*, “...a needle hub having a collar...a shield including a proximal end, a distal end and having at least one hinge, the proximal end of the shield being receivable by the collar in an interlocking engagement...”

Independent claim 91, as amended, of the present application recites, *inter alia*, “...a shield...having a linear bearing being hingedly connected to a portion of the shield disposed proximal to a distal end of the shield, the needle being slidably received by the linear bearing and the linear bearing being movable relative to the portion of the shield.”

The Nestell `020 patent in no way discloses or suggests a structural configuration as recited in amended claims 1, 5, 69 and 72. The Nestell `020 patent does not disclose, *inter alia*, a needle hub including a collar and a shield having a proximal end receivable by the collar in an interlocking engagement. The Nestell `020 patent in no way discloses or suggests a structural configuration as recited in amended claim 91. The Nestell `020 patent does not disclose, *inter alia*, a shield having a linear bearing hingedly connected to a portion of the shield disposed proximal to a distal end of the shield, the needle being slidably received by the linear bearing and the linear bearing being movable relative to the portion of the shield. Because of the above distinctions, it is respectfully submitted that independent claim 1, claim 2 depending therefrom, independent claim 69, claim 70 depending therefrom, independent claim 72, independent claim 91 and claim 92 ultimately depending from independent claim 5, patentably distinguish and are not obvious over the Nestell `020 patent. Reconsideration and withdrawal of the rejections are respectfully requested.

In the Office Action, claims 5, 7, 10-11, 27-28, 63 and 65 were rejected under 35 U.S.C. §102(e) over U.S. Patent No. 6,171,284 to Kao et al. (Kao `284). However, it is respectfully submitted that independent claim 5, claims 7, 11, 27-28, 63 and 65 ultimately depending therefrom, clearly and patentably distinguish over the Kao `284 patent. Claim 10 is cancelled without prejudice.

The Kao `284 patent in no way discloses or suggests such a structural configuration as recited in claim 5, as amended. The Kao `284 patent does not disclose, *inter alia*, a shield having a proximal end, a distal end and a lock disposed therebetween, the proximal end of the shield being receivable within a collar of a needle hub in an interlocking engagement, the shield being manually extensible from a retracted position to an extended position wherein the lock captures a portion of the needle disposed proximal to the distal end of the needle in a configuration to prevent displacement of the shield from the extended position and the distal end of the shield encloses at least a portion of the distal end of the needle.

Because of the above distinctions, it is respectfully submitted that independent claim 5, claims 7, 11, 27-28, 63 and 65 ultimately depending therefrom, patentably distinguish and are not obvious over the Kao `284 patent. Reconsideration and withdrawal of the rejections are respectfully requested.

In the Office Action, claims 5, 6, 10-16, 18-20 and 23 were rejected under 35 U.S.C. §102(b) over International Publication No. 97/31666 to Injectimed, Inc. et al. (Injectimed `31666). However, it is respectfully submitted that independent claim 5, claims 6, 11, 14-16, 18-20 and 23 ultimately depending therefrom, clearly and patentably distinguish over the Injectimed `31666 publication. Claims 10, 12 and 13 are cancelled without prejudice.

The Injectimed `31666 publication in no way discloses or suggests such a structural configuration as recited in claim 5, as amended. The Injectimed `31666 publication does not disclose, *inter alia*, a shield having a proximal end, a distal end and a lock disposed therebetween, the proximal end of the shield being receivable within a collar of a needle hub in an interlocking engagement, the shield being manually extensible from a retracted position to an extended position wherein the lock captures a portion of the needle disposed proximal to the distal end of the needle in a configuration to prevent displacement of the shield from the extended position and the distal end of the shield encloses at least a portion of the distal end of the needle.

Because of the above distinctions, it is respectfully submitted that independent claim 5, claims 6, 11, 14-16, 18-20 and 23 ultimately depending therefrom, patentably distinguish and are

not obvious over the Injectimed `31666 publication. Reconsideration and withdrawal of the rejections are respectfully requested.

In the Office Action, claim 64 was rejected under 35 U.S.C. §103(a) over the Kao `284 patent or the Injectimed `31666 publication. However, it is respectfully submitted that claim 64, ultimately depending from independent claim 5, clearly and patentably distinguishes over the Kao `284 patent and the Injectimed `31666 publication, including any combination thereof.

The Kao `284 patent or the Injectimed `31666 publication in no way disclose or suggest a structure as recited in amended claim 5, as discussed. Further, the double walled needle recited by amended claim 64 is not obvious, but a patentable and not obvious claimed element of Applicants' medical needle shield apparatus. Reconsideration and withdrawal of the rejection is respectfully requested.

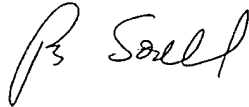
In view of the foregoing amendments and remarks, it is respectfully submitted that Claims 1-9, 11, 14-20, 23, 25, 27-31, 60, 62-65, 69, 70-72, 91 and 92 presently pending in the application are believed to be in condition for allowance and patentably distinguish over the art of record. An early notice thereof is earnestly solicited.

If the Examiner should have any questions concerning this communication or feels that an interview would be helpful, the Examiner is requested to call the Applicants' undersigned attorney.

Please charge any deficiency as well as any other fees that may become due at any time during the pendency of this application, or credit any over payment of such fees to deposit

account no. 50-0369. Also, in the event that any extensions of time for responding are required for the pending application, please treat this paper as a petition to extend the time as required and charge deposit account no. 50-0369 therefor.

Respectfully submitted,



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APPENDIX I

1. (Amended) A medical needle shield apparatus comprising:

a monolithic needle hub including a collar; and

a shield having a proximal end receivable by the collar in an interlocking engagement and including a plurality of hingedly connected segments, the shield being extensible between a retracted position and an extended position.

5. (Amended) A medical needle shield apparatus comprising:

a needle hub having a collar defining an interior cavity, the needle hub supporting a needle having a distal end; and

a shield having a proximal end, [and] a distal end and a lock disposed therebetween, the proximal end of the shield being receivable within the interior cavity of the collar in an interlocking engagement, the shield being manually extensible from a retracted position to [and] an extended position wherein the lock captures a portion of the needle disposed proximal to the distal end of the needle in a configuration to prevent displacement of the shield from the extended position and the distal end of the shield encloses at least a portion of the distal end of the needle.

69. (Amended) A medical needle shield apparatus comprising:

a needle hub means for supporting a needle having a distal end; and

a shield means, having a proximal end, a distal end and a lock disposed therebetween, for engaging the needle hub means in an interlocking engagement, the shield means being manually extensible between a retracted position and an extended position wherein the lock captures a portion of the needle disposed proximal to the distal end of the needle in a configuration to prevent displacement of the shield means from the extended position and the distal end of the shield means encloses at least a portion of the distal end of the needle.

72. (Amended) A medical needle shield apparatus comprising:

a needle hub having a collar and supporting a needle having a distal end;

a shield including a proximal end, a distal end and having at least one hinge, the proximal end of the shield being receivable by the collar in an interlocking engagement; and

a relief formed adjacent the at least one hinge and configured to flex inwardly.

91. (Amended) A medical needle shield apparatus comprising:

a needle; and

a shield being extensible to an extended position, the shield having a linear bearing being hingedly connected to a portion of the shield disposed proximal to a distal end of the shield, the needle being slidably received by the linear bearing and the linear bearing being movable relative to the portion of the shield.